



C-MAC videolaryngoscope compared with direct laryngoscopy for rapid sequence intubation in an emergency department: A randomised clinical trial

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Abstract: BACKGROUND Airway management in the emergency room can be challenging when patients suffer from life-threatening conditions. Mental stress, ignorance of the patient's medical history, potential cervical injury or immobilisation and the presence of vomit and/or blood may also contribute to a difficult airway. Videolaryngoscopes have been introduced into clinical practice to visualise the airway and ultimately increase the success rate of airway management. OBJECTIVE The aim of this study was to test the hypothesis that the C-MAC videolaryngoscope improves first-attempt intubation success rate compared with direct laryngoscopy in patients undergoing emergency rapid sequence intubation in the emergency room setting. DESIGN A randomised clinical trial. SETTING Emergency Department of the University Hospital, Zurich, Switzerland. PATIENTS With approval of the local ethics committee, we prospectively enrolled 150 patients between 18 and 99 years of age requiring emergency rapid sequence intubation in the emergency room of the University Hospital Zurich. Patients were randomised (1 : 1) to undergo tracheal intubation using the C-MAC videolaryngoscope or by direct laryngoscopy. INTERVENTIONS Owing to ethical considerations, patients who had sustained maxillo-facial trauma, immobilised cervical spine, known difficult airway or ongoing cardiopulmonary resuscitation were excluded from our study. All intubations were performed by one of three very experienced anaesthesia consultants. MAIN OUTCOME MEASURES First-attempt success rate served as our primary outcome parameter. Secondary outcome parameters were time to intubation; total number of intubation attempts; Cormack and Lehane score; inadvertent oesophageal intubation; ease of intubation; complications including violations of the teeth, injury/bleeding of the larynx/pharynx and aspiration/regurgitation of gastric contents; necessity of using further alternative airway devices for successful intubation; maximum decrease of oxygen saturation and technical problems with the device. RESULTS A total of 150 patients were enrolled, but three patients had to be excluded from the analysis, resulting in 74 patients in the C-MAC videolaryngoscopy group and 73 patients in the direct laryngoscopy group. Tracheal intubation was achieved successfully at the first attempt in 73 of 74 patients in the C-MAC group and all patients in the direct laryngoscopy group ($P = 1.0$). Time to intubation was similar (32 ± 11 vs. 31 ± 9 s, $P = 0.51$) in both groups. Visualisation of the vocal cords, represented as the Cormack and Lehane score, was significantly better using the C-MAC videolaryngoscope ($P < 0.001$). CONCLUSION Our study demonstrates that visualisation of the vocal cords was improved by using the C-MAC videolaryngoscope compared with direct laryngoscopy. Better visualisation did not improve first-attempt success rate, which in turn was probably based on the high level of experience of the participating anaesthesia consultants. TRIAL REGISTRATION Clinicaltrials.gov identifier NCT02297113.

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ORIGINAL ARTICLE

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A randomised clinical trial

Simon Sulser*, Dirk Uebmann*, Martin Schlaepfer, Martin Brueesch, Georg Goliasch, Burkhardt Seifert, Donat R. Spahn and Kurt Ruetzler

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MAIN OUTCOME MEASURES First-attempt success rate served as our primary outcome parameter. Secondary outcome parameters were time to intubation; total number of intubation attempts; Cormack and Lehane score; inadvertent oesophageal intubation; ease of intubation; complications including violations of the teeth, injury/bleeding of the larynx/pharynx and aspiration/regurgitation of gastric contents; necessity of using further alternative airway devices for successful intubation; maximum decrease of oxygen saturation and technical problems with the device.

RESULTS A total of 150 patients were enrolled, but three patients had to be excluded from the analysis, resulting in 74 patients in the C-MAC videolaryngoscopy group and 73 patients in the direct laryngoscopy group. Tracheal intubation was achieved successfully at the first attempt in 73 of 74 patients in the C-MAC group and all patients in the direct laryngoscopy group ($P = 1.0$). Time to intubation was similar (32 ± 11 vs. 31 ± 9 s, $P = 0.51$) in both groups. Visualisation of the vocal cords, represented as the Cormack and Lehane score, was significantly better using the C-MAC videolaryngoscope ($P < 0.001$).

CONCLUSION Our study demonstrates that visualisation of the vocal cords was improved by using the C-MAC videolaryngoscope compared with direct laryngoscopy. Better visualisation did not improve first-attempt success

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Introduction

Securing the airway is a fundamental priority in the treatment of critically ill or injured patients. In the emergency department (ED), direct laryngoscopy is the primary method for performing tracheal intubation and can be challenging, as patients often suffer from life-threatening conditions and reduced physiological reserves.¹ Apart from the mental stress, ignorance of the patient's medical history and record, potential anatomical or pathological factors, including cervical injury or immobilisation, and the presence of vomit and/or blood may complicate direct visualisation of the airway. Even in experienced hands, along with regular training and practice, successful tracheal intubation sometimes requires additional tools.^{2,3}

During the last decade, videolaryngoscopes have been introduced into clinical practice and have become increasingly common in elective procedures. Videolaryngoscopes can facilitate tracheal intubation by providing an improved view of the larynx and direct observation of the tracheal tube during passage through the vocal cords.^{1–5} As a result, videolaryngoscopy may decrease intubation difficulties and ultimately increase first-attempt and overall intubation success rate.

The C-MAC videolaryngoscope (Karl Storz, Tuttlingen, Germany) is a videolaryngoscope conceptually and structurally different from other models. The most important advantage of the C-MAC equipped with a Macintosh blade is that the Macintosh blade is the most common direct laryngoscopy blade and has been considered the 'gold standard' for direct laryngoscopy for many decades.

The C-MAC videolaryngoscope has been investigated in elective hospital procedures, out-of-hospital settings and in manikins, with promising results.^{6–11} As patients in the emergency room might be more challenging than patients undergoing elective anaesthesia, the aim of this study was to investigate the clinical performance and efficacy of the C-MAC videolaryngoscope compared with direct laryngoscopy in a randomised manner. Specifically, we wanted to test the hypothesis that the C-MAC videolaryngoscope improves the first-attempt intubation success rate compared with direct laryngoscopy in patients undergoing emergency rapid sequence tracheal intubation (RSI) in the emergency room setting.

Methods

After approval by the local ethics committee (Kantonale Ethikkommission Zurich – application number 2014–356, chair Professor Peter Meier-Abt), we prospectively

included 150 patients aged between 18 and 99 years undergoing emergency RSI in the emergency room of the University Hospital, Zurich between November 2014 and December 2015. Patients were informed verbally about the nature, relevance and impact of the project, and their oral consent was obtained. As this was sometimes limited because of acute illness or injury of the patient, written informed assent from an independent physician representing the rights of the patient was simultaneously obtained prior to intubation. Owing to ethical considerations, patients suffering from major maxillofacial trauma, patients with an immobilised cervical spine, patients with an indication for awake fiberoptic guided intubation, and patients with ongoing cardiopulmonary resuscitation were not included. The study protocol was registered at www.clinicaltrials.gov (NCT02297113) and previously published.¹² Prior to randomisation, the Mallampati score, weight, height, mouth opening, thyromental distance and head extension (0°, 15°, 30° or 45°) were assessed.

Eligible patients were randomly assigned to one of two groups: C-MAC videolaryngoscopy with an appropriately sized Macintosh blade; or direct laryngoscopy with an appropriately sized Macintosh blade. Randomisation (1:1) was based on computer-generated codes maintained in identical, opaque envelopes that were opened immediately before intubation.

All patients received standard monitoring, including ECG, arterial blood pressure (invasive or noninvasive) and oxygen saturation (SpO₂). Tracheal tubes were prepared with a hockey stick-shaped stilette. The backward, upward and rightward pressure manoeuvre was applied as indicated in all patients. Patients were placed in a supine position and tilted anti-Trendelenburg (about 30°). Anaesthesia for RSI was induced with fentanyl, propofol or thiopental, and succinylcholine or rocuronium, whichever was clinically appropriate. After complete muscle relaxation, confirmed by absence of palpable twitches in response to supramaximal train-of-four 1-Hz stimulation of the ulnar nerve at the wrist, the trachea was intubated as gently as possible. Intubation was performed by one of three experienced anaesthesia consultants. The videolaryngoscope was inserted into the oral cavity under direct vision. Visualisation of the vocal cords and insertion of the tracheal tube were performed using the video screen. An intubation attempt was defined as insertion of the laryngoscope through the mouth. An intubation attempt was terminated because of clinical considerations such as

desaturation or necessity to change the patient's positioning. Further anaesthesia management was independent from this study protocol and followed local standards of care.

Successful first-attempt tracheal intubation, confirmed by continuous capnography, served as our primary outcome. Time to intubation, defined as time between insertion of the blade into the mouth until detection of end-tidal CO₂, total number of intubation attempts, Cormack and Lehane score, inadvertent oesophageal intubation, ease of intubation (1, very easy; 2, easy; 3, somewhat difficult; 4, difficult; 5, impossible), complications, including dental trauma (visually assessed immediately after intubation), injury/bleeding of the larynx/pharynx, aspiration/regurgitation of gastric contents, the need for an alternative airway device for successful intubation (if randomised airway device failed), maximum decrease of oxygen saturation, and technical problems with the device served as secondary outcomes.

In the emergency setting, the first intubation attempt success rate is the most important clinical outcome parameter. Based on previous publications,^{1,6} we assumed a success rate of 99% for the C-MAC intubation and 85% for direct laryngoscopy. We calculated an estimated total sample size of 144 (72 per group) with a power of 80% and an α level of 0.05. Because of potential dropouts, we planned to include 150 patients in this study.

Statistics

Data are presented as mean \pm SD or absolute numbers and percentage (%). Differences with regard to intubation success were reported with 95% Wilson confidence intervals (CI). Differences with regard to time to intubation were reported with 95% CI based on normal distribution. Binary data were compared using Fisher's exact test and all other data were compared by the Wilcoxon–Mann–Whitney test. Exact two-tailed *P* values were calculated in SPSS for MAC (IBM SPSS Statistics, Version 22.0, Armonk, New York, USA). *P* < 0.05 was considered significant.

Results

Overall, 150 patients were included and randomised (75 patients in each group) into this study. Three patients (two from the direct laryngoscopy group and one patient from the C-MAC group) had to be excluded from the analysis: two patients requested to be withdrawn and one patient was excluded because of incomplete data documentation. Data from the remaining 147 patients (74 patients in the C-MAC group and 73 in the direct laryngoscopy group) underwent statistical analysis (Fig. 1).

Patient demographics, American Society of Anesthesiologists physical status, and airway characteristics did not differ between the groups (Table 1). Indications for RSI

are presented in Table 2. Apart from one patient in the C-MAC group, tracheal intubation was achieved at the first attempt in all other patients. Thus no difference between the two groups was evident (difference 1%, 95% CI –4 to +7%, *P* = 1.0). Time to intubation (32 ± 11 vs. 31 ± 9 s, difference 2, 95% CI –2 to +5 s, *P* = 0.51), maximum decrease in oxygen saturation (1 ± 2 vs. $1 \pm 2\%$, *P* = 0.95), and ease of intubation (1.5 ± 0.8 vs. 1.7 ± 0.9 , *P* = 0.18) were similar in the C-MAC and direct laryngoscopy groups.

Visualisation of the vocal cords, represented as the Cormack and Lehane score, was significantly better in the C-MAC group than in the direct laryngoscopy group (*P* < 0.001, Fig. 2). Grade 1 was reported in 81% in the C-MAC group and 50% in the direct laryngoscopy group. Grade 2a was reported in 11 and 32%, Grade 2b in 7 and 18%, and Grade 3 in 1% in the C-MAC group and none in the direct laryngoscopy group. Grade 4 was not documented in any patient.

We did not encounter any technical problems, dental injuries or any oesophageal intubation. Use of an alternative device was unnecessary in any patient.

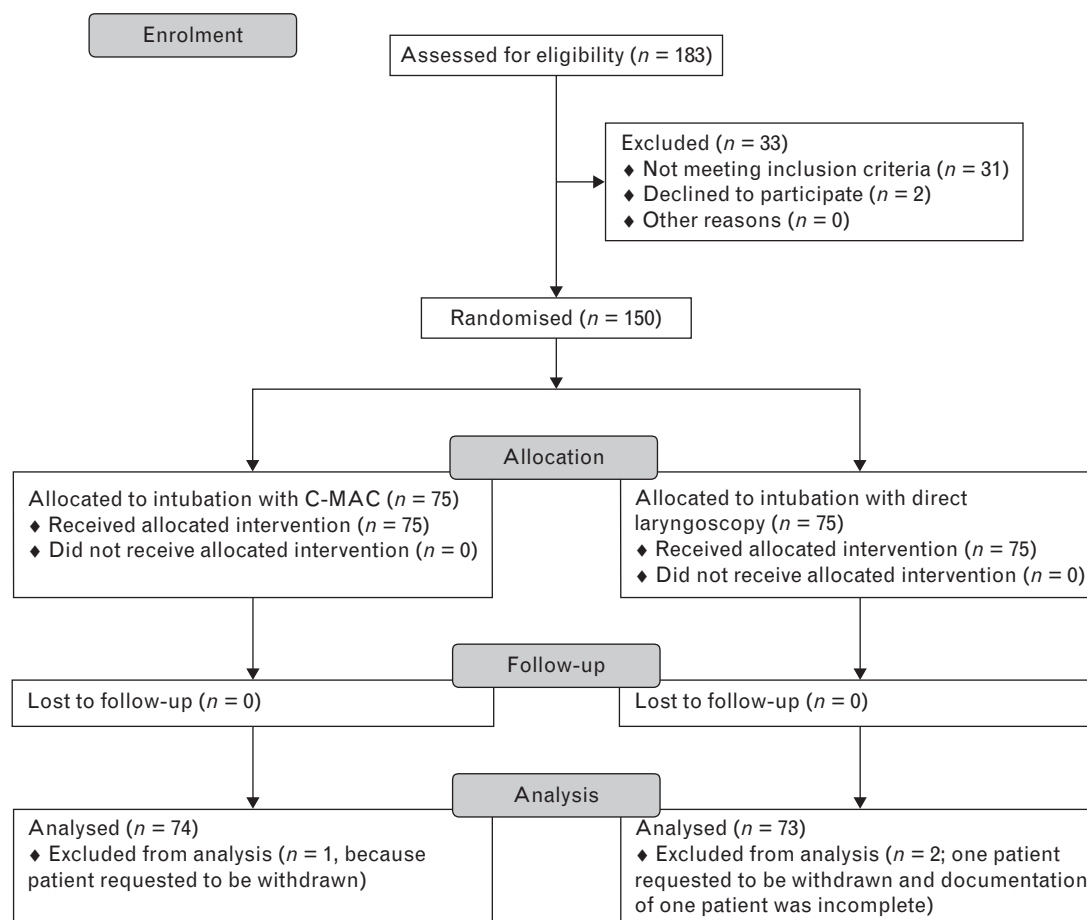
Discussion

The most important finding of our study is that the C-MAC provided better visualisation of the glottis, but this was not associated with higher first-attempt intubation success rate compared with direct laryngoscopy. Although this may be surprising or confusing at first glance, this finding might be based on the overall high level of experience of the anaesthesia consultants who performed the intubations in our study.

RSI is indicated in all patients who are considered not fasted and/or have an increased risk of gastric regurgitation and aspiration.¹³ The main objective of this technique is to minimise the time interval between loss of protective airway reflexes and tracheal intubation with a cuffed tracheal tube. This period is most critical, because aspiration of gastric contents may occur.¹⁴ In the emergency setting, all patients are strictly considered not fasted and RSI is thus indicated. However, RSI *per se* is associated with a higher risk of aspiration, increased haemodynamic instability and necessity for vasopressors, and oxygen desaturation.

Sakles *et al.*¹ published a retrospective study comparing the C-MAC videolaryngoscope with Macintosh-guided direct laryngoscopy for tracheal intubation in the ED. During the study period, the overall success rate in the C-MAC group was 98%, and therefore, comparable with our findings (100% overall success rate). Interestingly, the authors described an overall success rate of only 84% in the direct laryngoscopy group. These findings are in line with another randomised crossover study by Cavus *et al.*⁶ investigating 150 patients undergoing elective tracheal intubation in the elective operating room setting, and

Fig. 1



Study flow diagram.

reporting 88% (direct laryngoscopy) and 100% (C-MAC) overall success rate. Both studies are in major contrast to our findings, as we had a 100% success rate in the direct laryngoscopy patients. This might be based on the personal skill level and experience of the intubating

anaesthesiologist. Although tracheal intubation was performed mostly by emergency residents in the study by Sakles *et al.*, only three anaesthesia consultants with at least 7 years of clinical experience undertook tracheal intubation in our study.¹ The level of experience in the study by Cavus *et al.* remains unclear.⁶

The results of our study confirm prior findings by several studies investigating the C-MAC in several out-of-hospital emergency settings and reporting an overall intubation success rate ranging between 97.4 and 100%.^{15,16} Recently, in a randomised trial comparing the C-MAC

Table 1 Demographics and airway characteristics

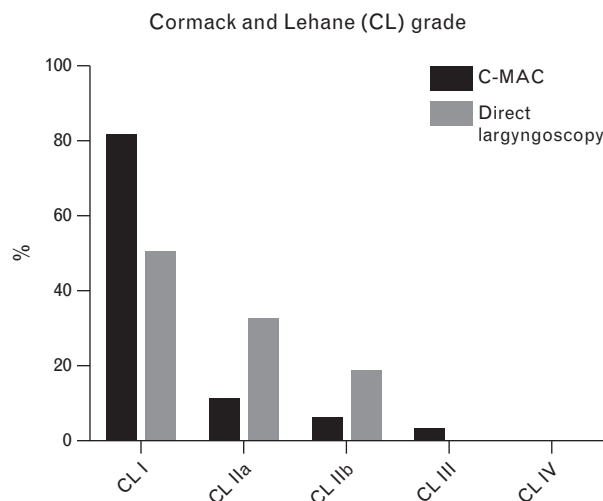
	C-MAC	Direct laryngoscopy
Age (years)	53 ± 21	54 ± 17
Male sex	68	55
Weight (kg)	75 ± 19	76 ± 18
Height (cm)	172 ± 13	171 ± 9
Mouth opening (cm)	5 ± 1	5 ± 1
Head extension (°)	39 ± 10	40 ± 9
ASA physical status		
1	20	23
2	38	37
3	31	33
4	11	7
5	0	0

Data are presented as mean ± SD or number as percentage of all patients. ASA, American Society of Anesthesiologists.

Table 2 Indications for rapid sequence induction (n = 147 patients)

Minor trauma (including extremities)	58
Major trauma (including head, thoraco-abdominal, pelvis, spine)	28
Multiple trauma	2
Acute abdomen (including ileus)	37
Gastrointestinal bleeding	11
Sepsis	8
Others (including bleeding)	3

Fig. 2



Laryngeal visualisation of the vocal cords. CL I, full visualisation of the vocal cords; CL IIa, partial visualisation of the vocal cords; CL IIb, visualisation of only arytenoids and epiglottis; CL III, only epiglottis seen, none of glottis seen; CL IV, neither glottis nor epiglottis seen. CL, Cormack and Lehane.

and the GlideScope, Aziz *et al.*⁴ reported a first-attempt success rate of 93% using the C-MAC vs. 96% in the GlideScope group.

In general, videolaryngoscopy is not a technique to make tracheal intubation faster, although in our study, time to intubation was similar in both groups. Although time to intubation is easy to measure, and therefore, often serves as an outcome in many airway studies, clinical relevance seems to be questionable and offers only limited clinical importance. Of course, prolonged intubation procedures may contribute to overall morbidity, but failed and subsequent multiple intubation attempts are much more relevant. Unrecognised oesophageal intubation definitely causes disastrous clinical outcomes, including desaturation, aspiration of gastric contents or bradycardia.^{17–19} Even a single episode of recognised oesophageal intubation is of great clinical significance, as this is associated with increased risk of aspiration, cardiac dysrhythmias and cardiac arrest.²⁰ However, we did not observe any oesophageal intubation in our study.

Based on evidence, there is an international consensus that videolaryngoscopes offer significantly better laryngeal visualisation compared with direct laryngoscopy, as measured by the Cormack and Lehane classification. But it is still controversial and there are conflicting results about whether improved Cormack and Lehane views result in increased success of intubation.^{1,21–23} The results of our study clearly demonstrate that visualisation was significantly improved when using the videolaryngoscope. However, this was not associated with better clinical outcome, in the sense of a higher success rate

or decreasing time to intubation. However, visualisation of the airway on a monitor helps to teach less experienced providers in airway management and potentially decreases the rate of oesophageal tube misplacements.

Although several authors^{1,15} have previously described several technical problems in the use of the C-MAC, mostly caused by either fogging or lens contamination by blood or vomit, this was not observed in this study.

Our study has some limitations. Based on ethical considerations and duties of the local ethics committee, some important emergency patient subpopulations (on-going cardiopulmonary resuscitation, major maxillofacial trauma, immobilised cervical spine, indicated awake fiberoptic guided intubation) were not included in this study. However, the study was intended to focus on RSI in the ED and was not powered to compare the use of the C-MAC with direct laryngoscopy during predicted difficult airway intubation, which has been already investigated by Aziz *et al.*³ Another limitation of our study is that only three highly skilled staff anaesthesiologists performed tracheal intubation. Therefore, the results of this study cannot be applied to an overall intubation setting although a limited number of highly skilled anaesthesiologists decrease interindividual results and may thus contribute to highly reproducible results.

In conclusion, the use of the C-MAC videolaryngoscope provided significantly better visualisation of the glottis compared with direct laryngoscopy. Better glottic visualisation was not associated with increased first-attempt and overall intubation success rate, which might be based on the fact that only highly experienced anaesthesia consultants were involved in this study. Although not investigated in this study, the use of videolaryngoscopes and better glottic visualisation might decrease the rate of oesophageal misplacement because of direct visualisation and might increase first-attempt and overall success rate, especially in less-experienced anaesthesia providers.

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